From: Bill Jacobs
To: Jenny Seifert
Subject: RE: Potential New Zinc Phosphide Product
Date: 11/04/2009 03:16 PM

The scenario that you describe virtually begs for a field trial due to the bird-deterrent and bait-acceptance issues. The ag. extension unit at Oregon State U., Corvallis, should be able to help with such a study. I suggest checking with the States involved before contracting for trials with captive animals (and likely the wrong types of voles) to see whether your preferred approach would be OK with OR and WA.

▼ Jenny Seifert ---11/04/2009 01:18:38 PM---Hi Bill, The product in question is our current zinc phosphide with an additional ingredient that ha

From: Jenny Seifert <jseifert@neogen.com>
To: Bill Jacobs/DC/USEPA/US@EPA
Date: 11/04/2009 01:18 PM
Subject: RE: Potential New Zinc Phosphide Product

Hi Bill,
The product in question is our current zinc phosphide with an additional ingredient that has been shown to been an effective bird repellent. We are working with USDS-APHIS on the concurrent bird studies. While we do understand that the submission of efficacy studies on voles is not required, our main concern for this new formulation is for above ground use patterns - specifically in Oregon and Washington. Both of those states have requested that some sort of efficacy data for voles be presented. I also understand that the best scenario is always to work with an actual field study, but we would like to be able to submit data sooner than a field study would typically allow and that is why we are looking at alternative options for now.

Any input is always greatly appreciated.
Best,
Jenny

Jennifer J. Seifert
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-----Original Message-----
From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Wednesday, November 04, 2009 12:10 PM
To: Jenny Seifert
Subject: Re: Potential New Zinc Phosphide Product

Are you talking about controlling voles in orchards or in various other contexts?

Either way, actual field trials would be best. You might be able to obtain cooperation from university facilities that have done vole work in the past (e.g., Cornell, the V.P.I. & State University field station in Winchester, VA, if still active), U.C. Davis, etc.

Simulated field trials have been used as surrogates for field trials in instances in which more that one field test is required. The advantages of a simulated test are that environmental conditions can be controlled to a degree and that absolute counts of subjects can be made to indicate how many survived and how many died. The disadvantages of simulated trials are that they are done under unnatural conditions and do not detect whether environmental conditions affect bait integrity and/or efficacy.

A tank-test is a laboratory efficacy study, not a simulated field study. For a simulated field study, you would need a test environment that more closely resembles vole habitat.

If the new product is another grain-based bait for which you mainly want to assess for palatability to voles, a simulated field trial or a laboratory feeding trial would be sufficient. If the new product is a different sort of Zinc Phosphide bait altogether, you should field-test it. For tests with captive animals, a control group housed in a manner similar to that for each test group would be needed. For field trials, a "check" area which does not receive toxic bait must be monitored concurrently with the poisoned areas so as to control for other factors that might affect vole activity locally. Two methods of assessing vole activity would be needed. Depending upon circumstances, a field trial could be less expensive than a laboratory trial as no housing and husbandry of subjects would be required. You would need an experimental use permit if the unregistered product were to be used to treat a total area in excess of 10 land acres, including treated "buffer" zones outside of activity census areas.

We normally do not require submission of efficacy data for products claimed only to control voles. Although they serve as reservoir species for a number of diseases, they seldom are directly implicated in the transfer of those diseases to humans. The case is different with Peromyscus spp. mice. Although the requirement to submit efficacy data typically is waived for vole baits, the requirement to do the testing is not. See test notes to the table in 40 CFR Section 158.400.

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| From: |
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|Jenny Seifert
<jseifert@neogen.com> |
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| To: |
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|Bill
Jacobs/DC/USEPA/US@EPA
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| Date: |
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|11/04/2009 09:32
AM |
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| Subject: |
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|Potential New Zinc Phosphide
Product |

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Good morning Bill,
I am working on a new zinc phosphide product and we are approaching the stage where we are ready to proceed to the efficacy trials. We are planning on conducting a GLP study on wild voles in addition to the commensal rodents.

We are likely going to be working with Genesis Laboratories to conduct the studies, but before we start work on the protocols we thought is best to contact you on one point of clarification first. Would a "simulated field study" (utilizing large stock tanks) be acceptable to the Agency for the purpose of showing efficacy on voles?

Thanks in advance for your assistance.
Best Regards,
Jenny

Jennifer J. Seifert
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